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K003269

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510(k) SUMMARY

In accordance with the Food and Drug Administration Rule to implement provisions of the Safe Medical Devices Act of 1990 and in conformance with 21 CFR 807, this is to serve as a Summary of Safety and Effectiveness for the Sulzer Orthopedics Unicondylar Interpositional Spacer.

Submitter:	Sulzer Orthopedics Inc. 9900 Spectrum Drive Austin, Texas 78717 (512) 432-9900
Date:	October 16, 2000
Contact Person:	Mitchell A. Dhority Manager, Regulatory & Clinical Affairs
Classification Name:	21 CFR 888.3590 - Knee joint tibial (hemi-knee) metallic resurfacing uncemented prosthesis
Common/Usual Name:	Hemi-knee prosthesis
Trade/Proprietary Name:	Unicondylar Interpositional Spacer (UIS)

PRODUCT DESCRIPTION

Currently, arthroscopic debridements are performed regularly to address the pain and synovitis associated with early stage osteoarthritis; as many as half of those patients treated are estimated to have Grade III-IV chondromalacia. It is also estimated that failure occurs within 2 years in half of those treated. While the effectiveness of arthroscopic debridement is quite variable, it is clear that it does not address the mechanical alignment and laxity problems associated with the joint. Use of other options, such as knee arthroplasty and high tibial osteotomy (HTO), are more invasive, technically challenging and may compromise the joint to future treatment options. Anti-inflammatory medications have also been used to manage pain, but have limited effect on moderate arthritis and offer no solution in terms of repair to the joint.

The Unicondylar Interpositional Spacer was developed as an alternative to arthroscopy, HTO and knee arthroplasty treatments for those situations where limited degeneration/joint destruction exists. Instead of simply debriding soft tissues as in arthroscopy or resecting valuable unaffected bone and cartilage as in total knee replacement, this treatment allows for placement of a metallic "spacer" device into the joint space above the affected medial tibial plateau. The femur then articulates against the polished, curved surface of device. The device is intended to be used without cement and is held in place by its geometry and the surrounding soft tissue structures.

The device will be manufactured from either wrought cobalt chromium alloy (ASTM F1537) or forged cobalt chrome alloy (ASTM F799). The design is kidney shaped to mimic that of the medial tibial condyle; the shallow "dished" geometry allows for articulation with the femur. It is asymmetric (left and right components) and is available in seven sizes (30-54mm) and five thicknesses (1-5mm) to better restore joint alignment, tension and stability.

The surgical procedure to place the device is carried out in two stages. First, the posterior horn of the meniscus is debrided and resected arthroscopically. The device may then be inserted into the joint space above the affected medial tibial plateau via open surgical implantation.

Use of this device raises no new issues relative to safety or effectiveness and provides several potential advantages over other surgical options, including:

- Technically easier to implant than a unicompartmental total knee, high tibial osteotomy or meniscal transplant.
- Facilitates future conversion to total knee arthroplasty by eliminating the need for bone resections.
- Is surgically less invasive (e.g. unicompartmental treatment, smaller incision, fewer implant components required, no bone resection required).

SPECIFIC DIAGNOSTIC INDICATIONS

The Unicondylar Interpositional Spacer is intended for uncemented use in treatment of the following:

- Moderate degeneration of the medial compartment of the knee (grade III-IV chondromalacia) with no more than minimal degeneration (grade I-II chondromalacia, no loss of joint space) in the lateral condyle and patellofemoral compartments.

SUBSTANTIAL EQUIVALENCE

Substantial equivalence is based on comparison to the following preamendment devices:

- McKeever Hemiarthroplasty Prosthesis
- MacIntosh Hemiarthroplasty Prosthesis
- Sbarbaro Tibia Plateau Prosthesis

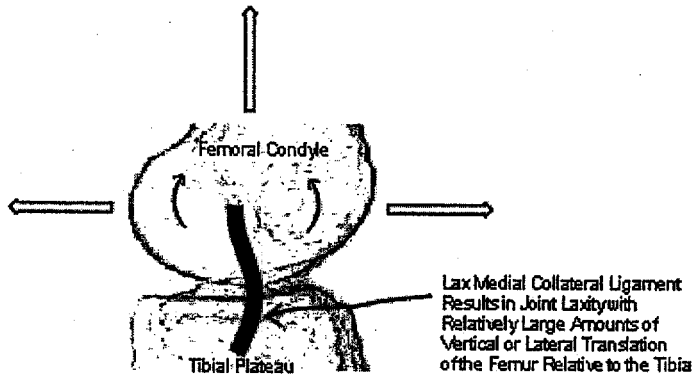
Design Features

The subject and predicate devices are similar in terms of design features. All of these designs are unicondylar in nature and generally incorporate a metallic tibial resurfacing component of various sizes/thicknesses. The femoral condyle articulates against the curved upper surface of the implant.

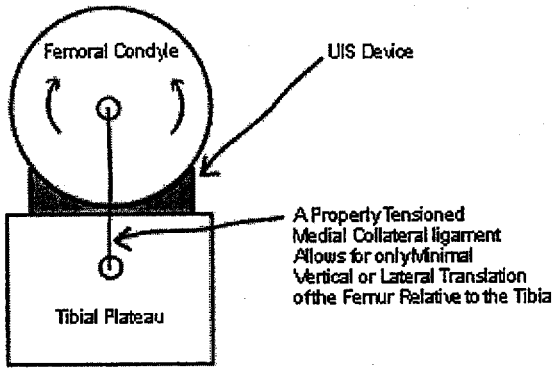
Stability

Like the MacIntosh tibial prosthesis, the Unicondylar Interpositional Spacer has no obvious means of attachment.

In the osteoarthritic knee, substantial amounts of articular cartilage have been lost as a result of the disease. The knee compartment suffers a subsequent closing of the joint spacing as seen on X-ray. This joint closing allows the collateral ligament to become lax and the joint to becomes unstable and off-axis (varus deformity). Whereas normal motion of the femoral condyle is largely rotational, if ligament laxity is present, there will be increased translational motion of the femur relative to the tibia



Filling the joint space that was once occupied by the now missing articular cartilage can restore the correct tension of the collateral ligament. When the proper thickness of the Unicondylar Interpositional Spacer is chosen, the tightening of the collateral ligament prevents any excessive translational motion of the femoral condyle. Thus, almost all of the forces against the Unicondylar Interpositional Spacer now become rotational and the Unicondylar Interpositional Spacer will have no forces acting on it that would cause it to "spit" from the joint space. The stability of the joint is restored.



The surface geometry of the Unicondylar Interpositional Spacer also plays a significant role in its inherent stability.

MacIntosh states "The collateral ligaments usually maintain their own length...and that the stability is maintained by a prosthesis that is thick enough to correct the deformity and take up the slack in the collateral ligaments". He further states that "The prosthesis is held in position by the anatomy of the knee joint, and stability depends on taut collateral ligaments. The top of the prosthesis has a contoured surface with rounded edges to provide the condyle with a permanent low friction area."

The Unicondylar Interpositional Spacer has a femoral surface geometry that imitates that of the tibial plateau including an intact meniscus. On the other side, the tibial surface of the Unicondylar Interpositional Spacer imitates the surface of the tibial plateau without the meniscus.

When the Unicondylar Interpositional Spacer is properly placed into the knee compartment, it rests inside the boundaries of the resected meniscus. It has substantially intimate contact with the tibial plateau throughout the entire range of motion. The femoral side of the Unicondylar Interpositional Spacer also has substantially full contact with the femoral condyle when the knee is in full extension.

Thus, when the knee is in full extension, the Unicondylar Interpositional Spacer can only be located in one position in the joint space as determined by the relative position of the femoral condyle to the tibial plateau.

As the knee is flexed and the femoral condyle begins to rotate, since the collateral ligaments remain under tension, the posterior aspect of the femoral condyle remains in contact with the central weight-bearing surface of the UIS

Materials

The subject and predicate devices are similar in terms of materials used. All of these designs use cobalt chrome alloy.

Intended Use

Additionally, the subject and predicate devices share similar indications for use. The subject device, like the predicate devices, are used generically in the treatment of unicompartmental tibial arthritis where total knee replacement is not warranted.

Clinical Safety & Effectiveness

Based on review of the published clinical literature on this type of device, the known potential risks associated with these devices are essentially of the same type and frequency as unicompartmental or total knee replacement, arthroscopy and others. As shown in the publications associated with the predicate devices, these risks include hematoma, infection, nerve palsy, embolus, dislocation, fracture and need for revision. The less invasive nature of the device also lends itself to ease of conversion to the more conventional surgical treatments.

The history with the predicate devices also indicates that the effectiveness of this treatment is at least equal to that obtained with tibial osteotomy in terms of pain relief, correction of deformity and restoration of stability. Furthermore, it provides some added benefits which cannot be recognized with current treatments (e.g., ease of implantation, ease of conversion to other treatments, less invasive).

Testing did not raise any new issues of safety or effectiveness and indicated that this device should provide performance equivalent to commercially marketed products.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JAN - 4 2001

Mr. Mitchell Dhority
Manager, Regulatory & Clinical Affairs
Sulzer Orthopedics, Inc.
9900 Spectrum Drive
Austin, Texas 78717

Re: K003269
Trade Name: Unicondylar Interpositional Spacer (UIS)
Regulatory Class: II
Product Code: HSH
Dated: October 17, 2000
Received: October 18, 2000

Dear Mr. Dhority:

We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. A substantially equivalent determination assumes compliance with the current Good Manufacturing Practice requirement, as set forth in the Quality System Regulation (QS) for Medical Devices: General regulation (21 CFR Part 820) and that, through periodic (QS) inspections, the Food and Drug Administration (FDA) will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, FDA may publish further announcements concerning your device in the Federal Register. Please note: this response to your premarket notification submission does not affect any obligation you might have under sections 531 through 542 of the Act for devices under the Electronic Product Radiation Control provisions, or other Federal laws or regulations.

This letter will allow you to begin marketing your device as described in your 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4659. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers Assistance at its toll-free number (800) 638-2041 or at (301) 443-6597, or at its Internet address "http://www.fda.gov/cdrh/dsmamain.html".

Sincerely yours,

for Mark N. Melkerson

Celia M. Witten, Ph.D., M.D.
Director
Division of General, Restorative and
Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

510(k) Number (if known): 003269

Device Name: Unicondylar Interpositional Spacer

Indications for Use:

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- Moderate degeneration of the medial compartment of the knee (grade III-IV chondromalacia) with no more than minimal degeneration (grade I-II chondromalacia, no loss of joint space) in the lateral condyle and patellofemoral compartments.

(PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

for Mark N Milhous

(Division Sign-Off)
Division of General Restorative Device
510(k) Number K003269 1/9/01

Prescription Use _____ OR Over-The-Counter Use _____

(Optional Format 1-2-96)